

REMARKS/ARGUMENTS

A. Status of the Claims

Claim 1 has been amended without prejudice.

New claims 9-16 have been added.

Support for the amendments to claim 1 and new claims can be found throughout the specification as filed and in the original claims. For example, support can be found in the following places of the specification as filed:

- at page 11, paragraphs 4 and 5 - “a pharmaceutical product for retention in the stomach. The product is produced by extrusion” and “The technology is a versatile system which can be used to deliver drugs in a sustained release manner”;
- at page 14, paragraphs 1 and 2 - “The sheet is made by extrusion of a mix of active ingredient and polymer”, “The mix is preferably extruded as a shaped sheet, and for example takes the form of a roll. As it is extruded the roll is cut to size” and “Redesigning only the extrusion mold can produce a prefolded sheet”;
- at page 15, paragraph 2 - “In another embodiment, the product of this invention comprises a sealed hollow tubular extrudate”; and
- at page 16, paragraph 2 – “Pelletisation by surface cutting will boost sealing of the two ends of the tubes.”

Support for new claim 9 can be found, e.g., at page 14, paragraph 1, of the specification as filed. Support for new claim 10 can be found, e.g., at page 14, paragraph 2, of the specification as filed. Support for new claim 11 can be found, e.g., at page 15, paragraph 2, of the specification as filed. Support for new claims 12 and 14 can be found, e.g., at page 14, paragraphs 1 and 2, of the specification as filed, wherein it is specified that the cut roll may be filled in a capsule, and in original claim 8 which specifies that the extruded forms are filled into a capsule. Support for new claim 13 can be found, e.g., towards the bottom page 15 of the

specification as filed, wherein there is a description of separate extrusion of the polymer and active ingredient.

Applicant respectfully submits that no new matter has been added by virtue of this amendment.

B. Specification

In the Office Action, the Examiner stated that “[a]n abstract on a separate page is required.” See Office Action, page 2.

In response, Applicant respectfully notes that the Manual of Patent Examining Procedure states that “[i]n an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need **not** submit an abstract commencing on a separate page if an abstract was published with the international application under PCT Article 21.” See MPEP, section 608.01(a) (emphasis added). The Manual of Patent Examining Procedure further states that “[t]he abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO.” See Id.

The present application is a U.S. national phase entry of International application No. PCT/GB03/02622. International application No. PCT/GB03/02622 was published as WO 03/105812, with the abstract appearing on the cover page of the publication.

Accordingly, Applicant respectfully submits that according to the Manual of Patent Examining Procedure it is not necessary for him to submit an abstract commencing on a separate page, because “[t]he abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO.” See MPEP, Section 608.01(a).

Therefore, withdrawal of the objection is respectfully requested.

C. Claim Rejections- 35 U.S.C. § 112

In the Office Action, claim 3 was rejected under 35 U.S.C. § 112, second paragraph, “as being indefinite” for containing the term “shaped.”

In response, Applicant submits that the term “shaped” has been deleted throughout the claim set.

Therefore, Applicant submits that the rejection is now moot.

D. Claim Rejections- 35 U.S.C. § 102

Claims 1 and 8 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 4,938,967 to Newton et al.

Claim 8 has been cancelled without prejudice.

Amended claim 1 is directed in part to an extrusion of a mix of a hydratable polymer and active ingredient using an extrusion mould designed to give an extrudate of specified forms which is cut to yield rolled sheets, prefolded sheets and sealed tubes.

The Newton reference describes an oral, solid, pharmaceutical dosage form that permits controlled release of a pharmaceutically active ingredient into the stomach. See, e.g., column 1, lines 4-9.

However, as the Examiner acknowledged on page 4 of the Office Action, the Newton reference does not describe, an extruded pharmaceutical product (i.e., extrudate) that is in the form of rolled sheets, prefolded sheets or sealed tubes as recited in the present claims.

Accordingly, Applicant submits that the Newton reference does not anticipate claim 1, which recite in part "cutting the extrudate to give a plurality of rolled sheets, prefolded sheets or sealed tubes."

Therefore, withdrawal of the rejection is respectfully requested.

E. Claim Rejections - 35 U.S.C. § 103

Claims 1 to 8 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 4,938,967 to Newton et al. in view of U.S. Patent No. 2,531,134 to Kropa.

This rejection is respectfully traversed. Applicant submits that the combination of the cited references even if properly combinable (a position which is traversed) would not have suggested to one skilled in the art a sustained release drug delivery system comprising an extrudate in the form of rolled sheets, prefolded sheets or sealed tubes as recited in amended claim 1, at the very least because there is no suggestion in either reference of a sustained release drug delivery system comprising an extrudate in the form of rolled sheets, prefolded sheets or sealed tubes as recited in claim 1.

Rather the cited reference (i.e., the Newton reference) teaches the skilled man, e.g., that the key to improving the gastric residence time of a pharmaceutical dosage form is to increase its density (column 4, lines 33-36). Hence, Applicant submits that the skilled man reading the Newton reference would look to use different ingredients (e.g. different binders) to achieve a high density product. Applicant further submits that this would not have prompted the skilled man towards the process now claimed, wherein the produced product (i.e., extrudate) is in specific forms, the forms which are not described in the cited reference.

Moreover, Applicant submits that the cited references would not have suggested to the skilled man that halogenated ethylene polymers (e.g., for making chemically resistant containers for pharmaceuticals) described in the Kropa reference are suitable for inclusion in the gastric controlled release solid units of the Newton reference.

Applicant further submits that the Kropa reference is concerned, e.g., with the production of halogenated ethylene polymers that can be used in a range of applications (e.g. it can be extruded into tubes useful as conduits for fluids or in the making of tough, resistant, coated wires – column 18, lines 15-17). However, Applicant notes that the only mention of pharmaceuticals in the Kropa reference is at column 18, lines 8-14, wherein it is stated that the polymers may be useful for making chemically resistant containers for pharmaceuticals. Accordingly, Applicant submits that the Kropa reference would not have suggested to the skilled man to use its polymers or methods in the preparation of a pharmaceutical product *per se*, let alone suggest that extruded sheets described therein might provide a pharmaceutical product with improved gastric retention as described in the Newton reference. Accordingly, Applicant submits that the skilled person would not have combined these references.

Therefore, Applicant also submits that the combination of the cited references does not render the present claims obvious, as the combination of the cited references would not have suggested to the skilled man the processes recited in the present claims.


Further, Applicant respectfully asserts that the rejection is based on a hindsight analysis.

For the foregoing reasons, withdrawal of the rejection is respectfully requested.

Conclusion

An early and favorable action on the merits is earnestly solicited. According to currently recommended Patent Office policy, the Examiner is requested to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
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